



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

9 MAY 2016

MEMORANDUM FOR ST

ATTN: DEBRA M NIEMEYER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled Association for the Accreditation of Human Research Protection Programs (AAHRPP): Accreditation Overview (Updated Version) presented at/published to Provision of AAHRPP info briefing to Defense Health Board with MDWI 41-108, and has been assigned local file #16175.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

*Reaccomplished due to
originators request on 8-May-16.
Originally signed 4/28/16.

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Debra M. Niemeyer, PhD, DAF, 59 MDW/ST	3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	4. PROTOCOL NUMBER: NA
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) NA			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Association for the Accreditation of Human Research Protection Programs (AAHRPP): Accreditation Overview (Updated Version)			
7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.			
<input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
<input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.)			
<input type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)			
<input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)			
<input type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.) Provision of AAHRPP info briefing to Defense Health Board (Note: Please clear NLT 15 Apr 2016)			
12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).			
DATE			
13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) LOPEZ, RAQUEL L; raquel.lopez.2.ctr@us.af.mil			14. DUTY PHONE/PAGER NUMBER 292-2097
15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Dr Josh Calcote	CTR	59 CRD (ST)	
b. Dr Earl Grant	GS14	59 CRD (ST)	
c.			
d.			
e.			
f.			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
16. AUTHOR'S PRINTED NAME, RANK, GRADE Debra Niemeyer PhD GS15		17. AUTHOR'S SIGNATURE NIEMEYER DEBRA M.1022593567 <small>Digitally signed by NIEMEYER DEBRA M.1022593567 DN: cn=NIEMEYER DEBRA M.1022593567, o=USAF Date: 2016.04.12 17:25:53 -0500</small>	18. DATE April 12, 2016
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Markus Gmehlin, Col, Vice Commander		20. APPROVING AUTHORITY'S SIGNATURE GMEHLIN.MARKUS.P.1087279320 <small>Digitally signed by GMEHLIN.MARKUS.P.1087279320 DN: cn=GMEHLIN.MARKUS.P.1087279320, o=USAF Date: 2016.04.14 16:38:37 -0500</small>	21. DATE April 14, 2016

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS		
1st ENDORSEMENT (59 MDW/SGVJ Use Only)		
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	22. DATE RECEIVED April 15, 2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16175
24. DATE REVIEWED 15 April 2016	25. DATE FORWARDED TO 502 ISG/JAC	
26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input type="checkbox"/> NO <input type="checkbox"/> YES If yes, give date. <input checked="" type="checkbox"/> N/A		
27. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED		
28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER COL LINDA STEEL-GOODWIN, USAF, BSC	29. REVIEWER SIGNATURE STEEL GOODWIN LINDA 1188463583	30. DATE April 15, 2016
2nd ENDORSEMENT (502 ISG/JAC Use Only)		
31. DATE RECEIVED	32. DATE FORWARDED TO 59 MDW/PA	
33. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED The slide show contains the required disclaimer. Although the disclaimer language is not verbatim from the JER, it clearly conveys the intent of the JER. There are no conflict of interest issues with the presentation of this slide show.		
34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Heather Slawson, 1Lt, Assistant Staff Judge Advocate	35. REVIEWER SIGNATURE SLAWSON HEATHER M 15169387 42	36. DATE 15 April 2016
3rd ENDORSEMENT (59 MDW/PA Use Only)		
37. DATE RECEIVED 20 April 2016	38. DATE FORWARDED TO 59 MDW/SGVJ 26 April 2016	
39. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Christopher Carwile, TSgt/E-6, NCOIC, PA	41. REVIEWER SIGNATURE CARWILE CHRISTOPHE R STEWART 1280477229	42. DATE 26 April 2016
4th ENDORSEMENT (59 MDW/SGVJ Use Only)		
43. DATE RECEIVED	44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE	
45. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED		
46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	47. REVIEWER SIGNATURE	48. DATE



59th Medical Wing



Association for the Accreditation of Human Research Protection Programs (AAHRPP): Accreditation Overview

Dr. Josh Calcote, CTR
Dr. Earl Grant, DAF
Clinical Investigations
and Research Support
Clinical Research Division
Science and Technology
59th Medical Wing
4 March 2016





Disclaimer

Warrior Medics – Mission Ready – Patient Focused



The opinions expressed in this presentation are solely those of the author(s) and do not represent an endorsement by or the views of the United States Air Force, the Department of Defense, or the United States Government.



Accreditation Process



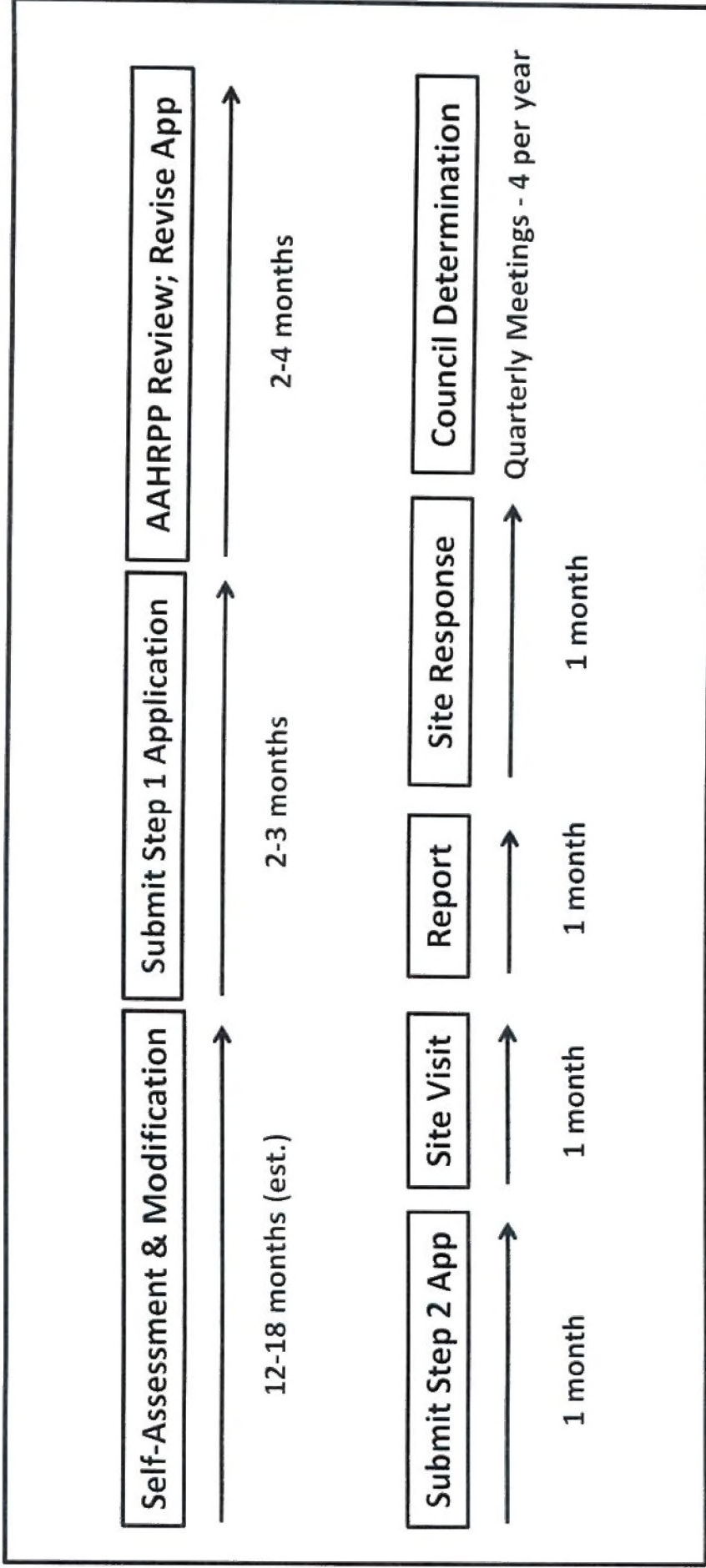
Warrior Medics – Mission Ready – Patient Focused

- **Self-Assessment** to identify gaps and make improvements
- **Submit Step 1** – an itemized, referenced document detailing how the organization meets each of the accreditation standards (~1,000 pgs.)
 - Reconcile issues identified by AAHRPP's Step 1 reviewer
- **Submit Step 2** and prepare for onsite evaluation by HRPP experts
 - Reconcile issues identified by AAHRPP's Site Visitors
- **AAHRPP Council review and determination** of accreditation status
 - Full Accreditation
 - Qualified Accreditation
 - Accreditation Pending
 - Accreditation Withheld



Accreditation Timeline

Warrior Medical Center – Mission Ready – Patient Focused





Activities To-Date

Warrior Medics – Mission Ready – Patient Focused

1. Self-Assessment/Gap Analysis
2. Chartered a 59 MDW HRRPP Steering Committee
3. Drafted HRRPP Medical Wing Instruction (MDWI)
4. Drafted Institutional Conflict of Interest MDWI
5. Revised/Drafted new IRB Operating Instruction.
6. Revised/Drafted new IRB Forms/Templates/Checklists/Letters
7. Revised/Drafted new Investigator Handbook
8. Created new public HRRPP webpage on 59 MDW website
9. Created new HRRPP and Conflict of Interest Training modules
10. IRB Assessment and Feedback mechanism for QA/QI
11. Generated QA/QI metrics for IRB turnaround times
12. Drafted AAHRRPP submission document (17 chapters)



The Way Forward



Warrior Medics – Mission Ready – Patient Focused

Create “HRPP Plan” (MDWI + Submission Document + IRB OIs)

- **Step 1:** Prepare Draft HRPP MDWI
- **Step 2a:** Domains prepare **Chs. 1-17** of AAHRPP Submission Document
- **Step 2b:** Incorporate Domain II IRB **OIs** into the Submission Document
- **Step 3:** HRPP Steering Cmte review of cover letter. **Start: 13 Jan 2016**
- **Step 4:** Receive comments/edits from Steering Cmte by: **1 Feb 2016**
- **Step 5a:** Submit HRPP MDWI for Wing approval. **Start: 14 Feb 2016**
- **Step 5b:** Submit all chapters and OIs to Steering Cmte. **ECD: Apr 2016**
- **Step 6:** Submit HRPP Plan for BOD review. **ECD: May 2016**
- **Step 7:** Submit HRPP Plan for 59 MDW/CC approval. **Target: Jun 2016**
- **Step 8:** After CC approval, submit AAHRPP Step 1 application. **ECD: Summer 2016**



Science & Technology

Warrior Medics – Mission Ready – Patient Focused



“Grow Medical Leaders, Drive Innovations in Patient Care and Readiness”